



## AGENDA

### Considerations Regarding Food and Drug Administration Review and Regulation of Articles for the Treatment of Rare Diseases; Public Hearing

Docket No. FDA-2010-N-0218

DATE	TIME	ORGANIZATION(S)	PRESENTER(S)
6/29/2010	9:00am-9:15am	Food and Drug Administration - Meeting Open -	Timothy Cote Elizabeth McNeil
6/29/2010	9:20am-9:40am	National Organization for Rare Disorders	Peter L. Saltonstall Frank Sasinowski
6/29/2010	9:40am-10:00am	Statistical Analysis Center Mailman School of Public Health	Seamus Thompson
6/29/2010	10:00am-10:20am	Amyloidosis Foundation	Mary E. O'Donnell
6/29/2010	10:20am-10:40am	MDJUNCTION.com Dercum's Disease Support Group	Diane Muffett
6/29/2010	10:40am-11:00am	Batten Disease Support and Research Association	Tracy VanHoutan
6/29/2010	11:00am-11:20am	Plasma Protein Therapeutics Association	Mary Gustafson
6/29/2010	11:20am-11:40am	Celiac Sprue Association	Mary Schluckebier
6/29/2010	11:40am-12:00pm	Rare Disease Advocacy Research Education Sun Valley Pharma Consult, LLC	Jonathan Jacoby Ron Browne
6/29/2010	12:00pm-1:00pm	LUNCH	
6/29/2010	1:00pm-1:20pm	Kakkis EveryLife Foundation	Emil D. Kakkis
6/29/2010	1:20pm-1:40pm	Caring for Carcinoid Foundation	Lauren Erb
6/29/2010	1:40pm-2:00pm	Eleos Incorporated	Dayton T. Reardan
6/29/2010	2:20pm-2:40pm	National MPS Society	Ernest Dummann Austin Noll Terri Klein
6/29/2010	2:40pm-3:00pm	Genetic Alliance	Sharon F. Terry
6/29/2010	3:20pm-3:40pm	Lundbeck Inc.	Mark Weinberg
6/29/2010	3:40pm-4:00pm	Addison and Cassidy	Chris Hempel
6/29/2010	4:00pm-4:20pm	Autoimmunity Research Foundation	Trevor G Marshall
6/29/2010	4:20pm-4:40pm	Dystonia Medical Research Foundation	Art Kessler
6/29/2010	4:40pm-5:00pm	Food and Drug Administration - Meeting Close -	Timothy Cote Elizabeth McNeil

The public hearing will be held on June 29, 2010, and June 30, 2010, from 9:00 a.m. to 5:00 p.m. ( White Oak Building 31 (Room 1503), 10903 New Hampshire Avenue, Silver Spring, MD 20993).

Webinar will be activated on June 29, 2010, and June 30, 2010, from 9:00 a.m. to 5:00 p.m. Webinar information is found at <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm>

\*Level of public participation will determine extension or early closure of public hearing.



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Date	Time	Organization/Contact	Presenter(s)
6/30/2010	9:00am-9:15am	Food and Drug Administration -Meeting Open -	Timothy Cote Elizabeth McNeil
6/30/2010	9:20am-9:40am	Advanced Medical Technology Association	Susan Alpert
6/30/2010	9:40am-12:00pm	Open Microphone for Public Comment	Shire Pharmaceuticals Sarcoma Foundation of America BioMarin Pharmaceutical Inc. Digestive Disease National Coalition *Additional Public Speakers
6/30/2010	12:00pm-1:00pm	LUNCH	
6/30/2010	1:00pm-4:40pm	Open Microphone for Public Comment	*Additional Public Speakers
6/30/2010	4:40pm-5:00pm	Food and Drug Administration - Meeting Close -	Timothy Cote Elizabeth McNeil

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